REMARKS

Claims 2, 6, 10, 15-21, 24 and 28-29 are pending in this application and are pres nted for reconsideration.

The indication that all the previous grounds of rejection have been overcome is noted with appreciation. However, claims 2, 6, 10, 15-21, 24 and 28-29 are now finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Yiv et al., U.S. Patent 6,245,349 in view of Weder WO 96/37192.

The examiner asserts that Yiv uses methods that do not need high shear mixing equipment, pointing to col.8, lines 19ff. The examiner admits that Yiv does not use ethanol but asserts that it is taught. The examiner asserts that WO '192 teaches similar dispersions using ethanol. Applicants respectfully traverse this rejection for the reasons which follow.

Yiv et al., U.S. Patent 6,245,349, is entitled DRUG DELIVERY COMPOSITIONS SUITABLE FOR INTRAVENOUS INJECTION. Yiv discloses injectable drug delivery compositions comprising

- between 3 and 50 percent by weight of a phospholipid,
- between 3 and 50 percent by weight of a compound selected from the group consisting of propylene glycol and polyethylene glycol having a weight average molecular weight of from 200 to 4000, and mixtures thereof, and
- between 3 and 50 percent by weight of a high HLB surfactant having an HLB value of at least about 12.

The drug delivery compositions of Yiv are to be administered to an animal to effect uptake of the active agent [cf. col. 2, lines 12ff], i.e. the use of the delivery composition of Yiv is limited to non-topical application. Col. 2, lines 15-19 state:

> "The primary mode of administration is by intravenous, intra-arterial, intrathecal, intraperitoneal, intraocular, intra-articular, intramuscular or subcutaneous injection. The preferred routes are intravenous, intrathecal or intra-arterial injection. The most preferred routes are intravenous or intra-arterial injection." [emphasis added]

In contrast thereto, the composition of the present invention can be used for the therapeutic treatment of the nervous system, endocrine system, cardiovascular system, respiratory tract, gastro-intestinal tract, kidn ys and efferent urinary tracts, locomotor apparatus, immunological system, skin and

mucosae and for the treatment of infectious diseases (see page 1, second par. of the present specification), i.e. the composition has a broad spectrum of uses and methods of application.

Applicants aver that one of ordinary skill in the art would not have been motivated to apply a very specific injectable drug delivery system which is directed to animals in general for the treatment of humans.

Furthermore it has to be noted that the propylene glycol/polyethylene glycol component of Yiv is essential for Yiv's drug delivery system. In contrast thereto, the present composition does not comprise propylene glycol and/or polyethylene glycol. The "essentially consisting of-language" of claims 28 and 29 precludes this component.

The Examiner states that lower primary alcohols can be used to form the concentrated compositions, but Yiv also teaches that "such alcohols are not preferred since they are disfavored for intravenous administration [cf. col. 7, line 13]." This latter teaching leads away from using lower primary alcohols like ethanol intravenously.

Weder, WO 96/37192, teaches the therapeutic or cosmetic use of sphingolipids and how to enable the preparation of suitable topical or parenteral dosage forms containing this specific active ingredient. As was discussed in detail in the pervious Amendment, the "essentially consisting of-language" of claims 28 and 29 precludes sphingolipids.

The Examiner further states that using ethanol to form an aqueous dispersion is conventional and dependant on the utility of the formulation. However, the '192, reference does not teach that ethanol is an essential component. On page 19 different pharmaceutical formulations are disclosed which may also be free of ethanol.

In summary, Yiv teaches injectable drug delivery systems comprising propylene glycol and/or polyethylene glycol as essential components, and Weder teaches drug and cosmetic compositions comprising sphingolipids as an essential component. Said components are all outside the claimed scope. Yet a proper combination of these references would retain all the essential components. Only hindsight would enable one to select certain essential components and to discard others.

Moreover, the references are so different that applicants aver ther is no motivation to combine the teachings of these references. When two teachings contradict each other without either having a corrective referenc to the oth r, the two references cannot be combined under 35 U.S.C. § 103(a). It is not possible in such a situation to predict with confidence that benefit would be found by choosing one route of modification over the other. This is just another way of saying that two references cannot be combined when the teaching of one destroys the teaching of the other. See *In re Gordon*, 221 USPQ 1125 (CAFC, 1984). However, even if the combination were proper, whatever the combination might suggest, it would not be the invention presently claimed. Therefore the combination of these 2 references is improper *per se* and should be withdrawn.

Reconsideration and withdrawal of the rejection of claims 2, 6, 10, 15-21, 24 and 28-29 under 35 U.S.C. § 103(a) as being unpatentable over Yiv et al., U.S. Patent 6,245,349 in view of Weder WO 96/37192, is respectfully solicited in light of the remarks *supra*.

Since there are no other grounds of objection or rejection, passage of this application to issue with claims 2, 6, 10, 15-21, 24 and 28-29 is earnestly solicited.

Applicants submit that the present application is in condition for allowance. In the event that minor amendments will further prosecution, Applicants request that the examiner contact the undersigned representative. Applicants note that an accompanying Notice of Appeal provides time for such an amendment.

Respectfully submitted,

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Enclosures: Petition for Extension of Time, Notice of Appeal

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